Minutes of the Drinking Water Committee Meeting
February 17-18, 1999

U.S. Environmental Protection Agency
Science Advisory Board
Drawbridge Estate Inn and Conference Center
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March 1, 1999

The Drinking Water Committee of the US EPA Science Advisory Board met on February 17-18, 1999 in Ft. Mitchell, KY, a site just outside the airport serving the greater Northern Kentucky and Cincinnati, Ohio areas. Cincinnati is the home of the US EPA National Center for Environmental Assessment (NCEA) Cincinnati, the major client for the meeting. The meeting was announced in the Federal Register at FR Vol. 64, No. 24, pp. 5795-5796; February 5, 1999 (see Attachment A). The agenda for the meeting is in Attachment B to these minutes. The purpose of the meeting was to complete the review of the NCEA-Cincinnati Comparative Risk Framework Methodology (CRFM) and to receive a briefing on the status of the agency report on the consumption of drinking water.

WEDNESDAY, FEBRUARY 17, 1999

Convene the Meeting , Dr. Richard Bull convened the meeting at 9:00 a.m. He welcomed all and noted the items for the agenda. He briefly noted the EPA stakeholder process that was underway and the DWC role in observing that process for the SAB. He mentioned the recent orientation and health effects meetings that had been held. Dr. Davis noted her observations based on attending the health effects workshop. Dr. Bull noted the expectations for the meeting and the need to draft the report to EPA on the comparative risk framework methodology (CRFM) that has to largely be drafted at this meeting.

Mr. Thomas Miller, SAB, Designated Federal Officer noted some recent SAB policy instructions that reflect the desire for prompt reporting by the Board and the need to consider independence of the advice given to the agency. He noted the issues that were relevant to disclosure and then the panelists introduced themselves and disclosed any items that they felt would be of interest to the public regarding any past interactions with the agency or others on issues relevant to drinking water science.

DWC members and consultants who were involved in this meeting included Drs. Richard Bull, Rhodes Trussell, L.D. McMullen, Verne Ray, Mary Davis, Yvonne Dragan, Anna Fan, Joel Pounds, Winston Harrington, Richard Gilbert, Lenore Clesceri, Edo Pellizzari, Judy Bean, John Evans, and Christine Moe. The panel was joined later in the day by Dr. Gary Toranzos and on the second day by Dr. Marylynn Yates. Agency and public attendees are noted on the sign in sheets which constitute Attachment C of these minutes.

Discussion of the Comparative Risk Framework Method

9:30 am; **a. Introductory Remarks**

1. Dr. Bull noted the past DWC efforts on the CRFM and stated the objectives for the day's discussions and writing efforts. The first meeting led to written comments reflecting individual member reactions to the background document and the briefing at the December 1998 meeting. Those comments were made a part of the minutes of that meeting. In addition, Dr. Bull compiled those comments into

a rough draft report from the DWC. The focus of this meeting is to discuss the issues raised in that compilation with the agency and to reach committee consensus on the contents of the DWC report on the issue. Two members questioned why this approach was taken rather than have the agency respond to the individual comments. Dr. Bull noted the procedures of the SAB that require reporting to go through the Executive Committee for approval and thence to the Administrator of EPA. Also, SAB comments are advice to the agency and it is within their discretion to take it or not in going forward with reports we review.

2. EPA Introductory Remarks, Dr. William Farland, Director EPA/NCEA, introduced the agency presentations for the day noting the CRFM provides a transparent and structured approach to evaluate data on the public health consequences associated with various drinking water treatment alternatives. NCEA sees the SAB review as a way to improve the CRFM. It hopes to discuss issues with the SAB in order to clarify specific issues raised at the first meeting. (See Attachment D)

   DWC members were interested in whether the CRFM was intended to ultimately be applied to other than drinking water issues. Dr. Farland indicated it was intended for drinking water first, but ultimately it would be useful in other situations where balancing a variety of risks was necessary. Examples of areas where it might have utility would be comparing particulate risk with dioxin risk or comparing the variety of risks that are common at Superfund sites.

3. Dr. Bull noted the rearrangements that had been made in the final charge to the DWC. The Committee and Agency representatives briefly discussed the restructured charge, noted changes, and agreed on its content. The panel agreed that it would discuss the case study results and the research needs at the end of the review instead of at the beginning as was implied by the charge. (See Attachment D)

10:00 am; **b. Discussion of the Comparative Risk Framework Method**

1. Dr. Patricia Murphy discussed the overall CRF Method noting the NCEA reactions to the individual DWC member comments that are contained in the draft compilation. She provided a general overview and identified and discussed the major points needing clarification, and proposed some actions on NCEA's part that might improve the CRFM in response to the DWC members' comments. Major points included the translation of critical health risks into measurable human health conditions, the selection of the QALY as a common health metric, the distinction of methods for comparing costs and benefits, and the economic costs of health conditions.

   The panelists noted that it will be important to bring visibility and clarity to these issues in the document. Currently, many important details are buried in the text and do not stand out. Another important addition would be to construct a section up front in the document that explicitly describes the process for handling uncertainty. (See Attachment E)

2. Dr. Richard Rheingans discussed the Quality Adjusted Life Year Measure (QALY). He noted the alternative approaches to deriving a common metric: a) using natural units such as number of cases–most useful when comparing alternatives directed at a single adverse event, b) converting mortality and incidence rate3s into measures of life lengthening/shortening–useful when alternatives affect multiple adverse events leading to significant mortality but not morbidity, and c) weighting or adjusting with subjective health related quality of life estimates–most useful when health conditions affect morbidity and mortality. The QALY was selected for the CRFM because it was judged to be more representative being based on population samples rather than expert assessment, it combines mortality with health related quality of life. He noted a number of limitations that NCEA would deal with in the revised document (E.G., limited representativeness, logistical problems in developing case by case QALYs). In dealing with the issues, NCEA will attempt to draw lessons in use of QALYs by other agencies dealing with medical and health issues. (See Attachment G)

   Panelists noted a better comparison between cost-effectiveness analysis and cost-benefit analysis could be developed. They noted that the QALY measures in this study came from one population and that population was probably not very representative of those dealt with in environmental health issues. A better discussion is needed to show how various factors lead to the QALY weights used and how other issues influence the metric (e.g., age, health history of respondents, etc.). In addition, members wondered if the method could distinguish among alternatives when the differences between risks were small as contrasted to the large microbial to cancer risk differentials in the case study. Some noted that the method should actually push decision making to the point where the method can not discriminate among alternatives. Members also noted that the structure brought to the issue by the method itself could be of great value even if the CRFM ultimately could not distinguish among risks associated with alternative treatments. That outcome frees the risk manager to decide on the basis of 'non-health' issues (e.g., taste or odor criteria). Finally, members noted that the report should try to identify situations in which the method may not be able to so discriminate.

3. Mr. Glenn Rice discussed general application points that can be drawn from the case study. He noted that the case study was prepared to demonstrate the utility of the CRFM. It is limited in scope and a number of issues mentioned by the panel have been intentionally excluded at this stage of the process (factors affecting source waters, engineering failure, distribution system effects and failure, financial cost of projected illnesses, additional pathogens and other common health metrics beyond the QALY). He asked if inclusion of additional issues would better illustrate the CRFM? He also noted that the CRFM does not make the decision: rather it informs the decision making process. The CRFM is intended to link treatment technology to health outcomes, provide a framework for including and evaluating various data sources and models, and makes assessment assumptions and uncertainty in the assessment explicit. He also noted factors associated with use of the CRFM at a variety of scales (local,

regional, and national). (See Attachment H)

Members noted that it is important to recognize that the simplifications in the case study make it inappropriate for use in ongoing regulatory actions by the Office of Water. Further the utility of the method would be lessened if the case study conclusions can only be reached by excluding the factors not included at this time.

Dr. Harvey noted for emphasis that the Case Study is not a decision document for standard setting. It is the first step in showing the methodology. An applications document will be prepared later to show how to handle issues that have been excluded from this first application of the CRFM. Further, the CRFM does not fit into the scheme of the Stage 2 process.

12:45 - 2:00 pm LUNCH

4. Dr. Josh Cohen discussed issues associated with the further treatment of uncertainty in the CRFM and the case study. (See Attachment I)

1:30 pm; **e. Discussion of Case Study Specifics, Dr. Terry Harvey and DWC Members**

1. Mr. Likens (EPA/NRMRL) noted a number of watershed management, source water characterization, treatment effectiveness, and distribution system issues that need to be further discussed in the revised document.

   Members noted that it would be good to point out the real world variables that are not included in the case study so people do not confuse it with a real-world analysis. It might also be helpful to include the concept of system reliability in the CRFM and to include the distribution system. (No handouts provided).

2. DBP Risk, Dr. Linda Teuschler discussed the complex mixtures risk estimation issues. She noted that NCEA agrees with the need to incorporate epidemiologic data into the estimates. However, she disagreed with comments suggesting that response addition was inappropriate for noncancer data. She presented a number of points in favor of response addition (guidelines default, Superfund precedents, studies by Gaylor et al., and the situation evaluated is a low level exposure case. (See Attachment J)

   Members noted that the assumptions regarding TOX could be too broadly applied and make the analysis appear more certain than merited. The uncertainty should be discussed clearly.

3. Dr. John Lipscomb noted a number of issues regarding DBP toxicity. Issues included differential weighting of toxicity endpoints used to arrive at health conditions, how to weight risks from low level exposure, how to convert continuous dose response data into a range of health effects, developmental toxicity, extrapolation of risk into the unidentified TOX components, additional

routes of DBP exposure, and incomplete treatment of mechanistic data. (See Attachment K)

Members were concerned that the mechanistic data be treated in a consistent manner. If mode of action data is discussed for one compound, others with comparable data should also be discussed, they should not be treated differently. They also noted that the translation of subtle health effects to overtly adverse health conditions needs to be further clarified.

4. Drs. Brenda Boutin and Mary Beth Brown discussed issues that are relevant to how pathogen risk is handled in the case study. (See Attachment L). They noted that though Cryptosporidium was the only microorganism used in this case study, eventually NCEA will need to test the CRFM using other protozoans, bacteria and viruses. They also noted issues associated with the way a number of factors are treated in the case study, e.g., infection and immunity, pathogen survival in distribution systems, strain-linked susceptibility, terminology use for waterborne pathogens, and endemic vs. outbreak levels of disease. They also noted that the model allows for the inclusion of more recent data

   Members were concerned with the use of a 12 week reinfection period that was assumed in the case study. An assumption such as this, used in the baseline case, implies more certainty in the results of the model than warranted by the facts. The figure was included without reference to its source and uncertainty as applied to the case study. The members noted that the agency should clearly identify what is known; i.e., they should be careful not to either overstate or understate what is known. Members also noted that gaps shown in the case study can help the agency identify important research needs.

5:15 p.m. **Adjourned for the Day**

THURSDAY, FEBRUARY 18, 1999

8:30 a.m. **Welcome and Recap from Day One**

1. Dr. Bull briefly recapped day one's activities. He noted the stakeholder activities that had occurred since the last DWC meeting in December 1998 and mentioned the need for a DWC observer for the upcoming ICR Stakeholder Workshop being held from march 10-12, 1999.

8:45 a.m. **Briefing by EPA Office of Water Representatives on the U.S. Water Consumption Report;** Julie Du and Helen Jacobs (OW/OS&T)

1. Drs. Julie Du and Helen Jacobs briefed the Committee on the status of EPA's efforts to determine drinking water consumption estimates for the U.S. This briefing provided background to the DWC in preparation for the SAB review of the agency report (probably at the end of May 1999) that will be conducted for the Executive Committee by members from the DWC and other SAB committees.

(See Attachments M1 - M3)

The presenters noted that existing consumption defaults are based on studies by Ershow and Cantor from 1989. Updates are needed as a result of more recent consumption data from USDA and because of the mandate of SDWA to identify subpopulations at elevated risk of health effects from exposure to contaminants in drinking water and to conduct studies characterizing health risk to sensitive populations from such contaminants. Estimates are to be generated on consumption by water source for different population **groups**: age, gender, race, socioeconomic status, geographic region, pregnant women, and lactating women. **Sources** considered will include community water supplies (tap), plain bottled water, and household cisterns/springs/etc. Water **types** will include direct water consumed as a beverage, indirect water added to foods and beverages during home/restaurant preparation, and intrinsic water in foods and beverages at the time of market purchase. The data used in generating the consumption estimates comes from USDA's Continuing Survey of Food Intake by Individuals (CSFII) for 1994-1996.

Members noted the desirability of including confidence intervals and medians for the estimates being generated to help in their interpretation. Also, members were interested in whether the estimates would reflect seasonality and whether they would reflect heated versus nonheated water. The members noted that since the actual review would be conducted by a joint SAB panel the Agency should recognize the dual perspectives that would likely emerge based on the focus normally reflected by the parent committees involved (the drinking water focused DWC and the broader exposure focused IHEC.

Mr. Miller noted that the International Bottled Water Association had submitted tabular data on bottled water marketing that it wished the DWC to receive. The material has been provided to the Agency (Du, Jacobs) and to the DWC members. It is also being made a part of these meeting minutes as Attachment N.

10:00 a.m. **DWC Planning for FY 1999** ;

1. The Chairman noted that three rules were due to come to the committee for review during the summer months. The date is not yet known. Drs. Yates and Toranzos noted that the ground water rule would likely go to OMB in April and that the preamble was already on the OW website. Members were reminded that their expertise that made them valuable to the DWC was the same that made them valuable to the agency and others who have an interest in these rulemakings. Members need to take care to maintain their independence so that they can participate in the reviews. If they are contacted and become involved in these specific matters for any of the participants they should keep the SAB/DWC DFO informed in writing of their involvement so any potential conflicts can be evaluated.

11:00 a.m. **DWC Writing Session for the CRFM Report**

The remainder of the meeting was taken up with discussing the draft member comment compilation and making writing assignments to panelists so that a revised document can be developed by the Chairman and the DFO. Assignments were requested to be completed by COB, Friday, February 26, 1999. The consensus document is scheduled for deliver to the panel for comment and concurrence by March 26, 1999.

2:55 p.m. **Adjourn the Meeting**

Dr. Bull adjourned the meeting at 2:55 pm.

I certify that these minutes are accurate to the best of my knowledge.

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Dr. Richard J. Bull	Mr. Thomas O. Miller
Chairman	Designated Federal Officer
Drinking Water Committee	Drinking Water Committee

ATTACHMENTS

A Federal Register Notice
B Agenda
C Sign-in Sheets
D Dr. Farland's Overheads
E Revised Charge
F Dr. Murphy's Overheads
G Dr. Rheingan's Overheads
H Mr. Rice's Overheads
I Dr. Cohen's Overheads
J Dr. Teuschler's Overheads
K Dr. Lipscomb's Overheads
L Drs. Boutin and Brown's Overheads
M Drs. Du and Jacob's Overheads
N International Bottled Water Association Public Submission

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